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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,493	12/28/2000	Mark A. Burns	UM-04985	3280
23535	7590 01/16/2003			
MEDLEN & CARROLL, LLP			EXAMINER	
101 HOWARI SUITE 350	D STREET		SISSON, BRADLEY L	
SAN FRANCISCO, CA 94105			ART UNIT	PAPER NUMBER
			1634	1
			DATE MAILED: 01/16/2003	71

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
è	09/751,493	BURNS ET AL.				
Office Action Summary	Examiner	Art Unit				
	Bradley L. Sisson	1634				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM						
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1) Responsive to communication(s) filed on 04	November 2002 .					
2a) ☐ This action is FINAL . 2b) ☑ T	his action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-20</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and	or election requirement					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received.						
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)	, 	(DTO 440) PersonNe(2)				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 Noti	view Summary (PTO-413) Paper No(s) ce of Informal Patent Application (PTO-152) r:				





DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 November 2002 has been entered.

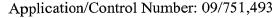
Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is noted that none of the claims currently before the Office are directed to conducting any reaction.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As presently worded, the claims encompass "microdroplet transport channels" of virtually any dimension. Page 8 of the specification, however, states"





"the channels can be between 0.35 and .5 um in depth (preferably 20 um) and between 50 and 1000 um in width (preferably 500 um), and the volume of the droplets can range (calculated from their lengths) between approximately one (1) and (100) nanoliters (more typically between ten and fifty)." The specification has not been found to provide an adequate support for any other range of dimensions for the channels. Accordingly, the specification does not reasonably support the position that applicant, at the time of filing, was in possession of channels that had a depth or width other than those broadly defined. A review of the disclosure of he priority documents also does not support the claim for priority in so far as applicant having provided an adequate written description of all possible microchannels. It is well settled that "[I]t is not enough for purposes of written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modification that the inventor might have envisioned, but failed to disclose." Lockwood v. American Airlines Inc. (Fed. Cir. March 1997) 41 USQP2d 1961 at 1966. Accordingly, applicant is urged to consider narrowing the scope of the claims to those embodiments adequately supported by the disclosure.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.





- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US Patent 5,922,591) in view of Wilding et al., (US Patent 5,587,128) and Yamaguchi et al. (US Patent 3,965,047).
- 9. Anderson et al., teach of a microfluidic device comprised of silicon that is comprised of transport channels therein. Column 20 discloses the use of insulating material such as silicon dioxide and that the channels may be coated with a substance that enhances hydrophobicity. It is suggested that this type of insulating material may be used in combination with "electrical leads" that have been placed in the channel. The aspect of an "electrical lead" is met by the deposition

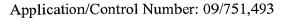




of a "metallic layer" on the surface of the channel. Dimensions of channels are disclosed at column 18.

- 10. While Anderson et al., disclose the inclusion of heating means, they do not disclose that the heating elements are arranged in an array format such that fluid transport is achieved.
- 11. Wilding et al., disclose mesoscale polynucleotide amplification devices that are comprised of minute channels formed, through various means, in a silicon base or substrate (column 5, last paragraph). Column 6, second paragraph, and columns 14-15, teach explicitly of optionally coating the surface of the reaction chamber and/or the channel walls (applicant's transport channels) with silicon dioxide.
- 12. Wilding et al., further disclose that the device, in at least one embodiment, comprises a series of heating means that are arranged along a common flow path. The intent of the heating elements in the disclosure is for the denaturation of nucleic acid, not for fluid transport.
- 13. Yamaguchi et al., teach using an array of heating elements so to achieve "differential heating."
- 14. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the aspect of an array of heating elements in a micro-channel with micro-scale channels and reaction chambers, fluid receiving means and organic materials such as cells and nucleic acids, as such would have afforded the ordinary artisan with a device that is capable of not only performing a variety of chemical/biochemical reactions such as PCR, but would have permitted such reactions to be done so in a device that self contains all of the required elements and reactants. In view of the well-developed nature of the devices and the reactions, the ordinary artisan would have had a reasonable expectation of success.





Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

- 16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.
- 17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. J. Sinon

Bradley L. Sisson Primary Examiner Art Unit 1634

BLS January 13, 2003